



BROOKS AUTOMATION, INC.

What you need to know about 2006/42/EC The New EU Machinery Directive

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Remember the date:

DECEMBER 29, 2009



As of that date...

98/37/EC is repealed

The OLD Machinery Directive

and

2006/42/EC is in effect

The NEW Machinery Directive



As of that date...

All products within scope sent into the EEA from that day forward must comply with the new MD

All DoC/DoIs for those products must comply with and reference the new MD



But...

Do not destroy the old DoC or DoI

Products that were shipped into the EU prior to implementation of the new MD need to maintain their TCF as it was and that includes the DoC or DoI

*(TCF as it was must be kept for 10 years
from the date of last production)*



Look beyond the EU...

- The new MD is a New Approach Directive and as such applies to the EEA

EEA comprises the EU Member States plus
Iceland, Norway, Liechtenstein



Scope

What is
INCLUDED
in the scope
of the new
Machinery Directive



Scope – what is included

A. Machinery

- An assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort consisting of linked parts or components, at least one of which moves, and which are joined together for a specific purpose*
- An assembly as noted above missing only the components to connect it on site to sources or energy and motion
- An assembly as noted in the two indents above ready to be installed and able to function as it stands only if mounted on a means of transport, or installed in a building or structure
- An assembly as noted in the three indents above or partly completed machinery (see item G) which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole
- An assembly of linked parts or components, at least one of which moves and are joined together, intended for lifting loads and whose only power source is directly applied human effort



Scope – what is included

A. Machinery (cont'd)

- * Article 24 of the new MD amends the Lifts Directive (95/16/EC) and so construction site hoists and lifts with a speed of 0.15 m/s or less are now within scope of the new MD. *[and are now excluded from the Lifts Directive]*



Scope – what is included

B. Interchangeable Equipment

- A device which, after the putting into service of machinery or of a tractor, is assembled with that machinery or tractor by the operator himself in order to change its function or attribute a new function, in so far as this equipment is not a tool

C. Safety Components

- Which serves to fulfill a safety function
- Which is independently placed on the market
- The failure and/or malfunction of which endangers the safety or persons, and,
- Which is not necessary in order for the machinery to function, or for which normal components may be substituted in order for the machinery to function
- An indicative list of safety components is set out in Annex V, which may be updated in accordance with,,,



Scope – what is included

D. Lifting accessories

- A component or equipment not attached to the lifting machinery, allowing the load to be held, which is placed between the machinery and the load or on the load itself, or which is intended to constitute an integral part of the load and which is independently placed on the market; slings and their components are also regarded as lifting accessories

E. Chains, ropes and webbing

- Designed and constructed for lifting purposes as part of lifting machinery or lifting accessories [*chains, ropes and webbing used for other purposes are not considered part of this definition*]



Scope – what is included

F. Removable mechanical transmission device

- A removable component for transmitting power between self-propelled machinery or a tractor and another machine by joining them at the first fixed bearing. When it is placed on the market with the guard it shall be regarded as one product

G. Partly completed machinery

- An assembly which is almost machinery but which cannot in itself perform a specific application. Partly completed machinery is only intended to be incorporated into or assembled with other machinery or other partly completed machinery or equipment, thereby forming machinery to which this Directive applies.



Scope

What is
EXCLUDED
in the scope
of the new
Machinery Directive



Scope – What is excluded

- The following products and those covered by a specific Directive (e.g., Lifts, Medical Devices, Pressure Equipment, Cable Ways, etc.)
 - a. Safety components intended to be used as spare parts to replace identical parts and supplied by the manufacturer of the original equipment
 - b. Specific equipment for use in fairgrounds and amusement parks
 - c. Machinery specifically designed or put into service for nuclear purposes which, in the event of a failure, may result in an emission of radioactivity



Scope – What is excluded

d. Weapons including firearms

- Impact machinery using a cartridge are not excluded, and they are now in the scope

e. The following means of transport with the exclusion of machinery mounted on these vehicles :

- Agriculture and forestry tractors for the risks covered by Directive 2003/37/EC;
- Motor vehicles and their trailers covered by Directive 70/156/EEC
- Vehicles covered by Directive 2002/24/EC relating to two or three wheel vehicles; motor vehicles exclusively intended for competition
- Means of transport by air, on water , and on rail networks

f. Seagoing vessels and mobile offshore units and machinery installed on board such vessels and/or units



Scope – What is excluded

- g. Machinery specifically designed and constructed for military or police purposes
- h. Machinery specifically designed and constructed for research purposes for temporary use in laboratories
- i. Mine winding gear
- j. Machinery intended to move performers during artistic performances



Scope – What is excluded

- k. Electrical and electronic products falling within the following areas, insofar as they are covered by the Low Voltage Directive, 73/23/EC
 - Household appliances intended for domestic use
 - Audio and video equipment
 - Information technology equipment
 - Ordinary office machines
 - Low-voltage switchgear and control gear
 - Electric motors
- l. The following types of high-voltage electrical equipment
 - Switch gear and control gear
 - Transformers



Presumption of conformity and harmonised standards

- Existing standards under the old MD can not be used for presumption of conformity to the new MD
- All standards used for the old MD are under review
- A new list of standards that can be used for a presumption of conformity will be published in 2009



Procedures for assessing conformity of machinery

- If the machinery is not in Annex IV
 - then the procedure in Annex VIII applies

- If the machinery is in Annex IV and is manufactured in accordance with one or more of the harmonised Directives
 - The procedure of Annex VIII, or
 - The EC type examination procedure in Annex IX and the internal checks on the manufacture as found in Annex VIII, or
 - The full quality assurance procedure as provided in Annex X



Procedures for assessing conformity of machinery

- If the machinery is in Annex IV and is not manufactured in accordance with one or more of the harmonised Directives
 - The EC type examination procedure in Annex IX and the internal checks on the manufacture as found in Annex VIII, or
 - The full quality assurance procedure as provided in Annex X



Annex 1

- Defines the Essential Health and Safety Requirements (ESHRs) relating to the design and construction of machinery
 - It does not apply to 'partly completed machinery' but may be applied and fulfilled in partly completed machinery and therefore may need to be referenced on the DoI
 - Risk assessment and risk reduction are now a priority in accordance with its importance
 - Covers the following areas:
 - General principles and General remarks
 - Control systems
 - Protection against mechanical hazards
 - Required characteristics of guards and protective devices
 - Fixing systems for guards MUST remain in place when the guard is removed.
 - Many other changes
 - Risks due to other hazards (slips, trips, falls, electrical, static electricity, thermal, acoustic, etc.)



Annex 1

- Maintenance
 - Information – warning devices, marking, manuals, labels, etc.
- ESHRs for certain types of machinery
 - Foodstuffs
 - Portable hand held and/or hand guided machinery
 - Machinery for working with wood and material with similar physical characteristics
- Supplementary ESHRs to offset hazards due to the mobility of machinery
- Supplementary ESHRs to offset hazards due to lifting operations
- Supplementary ESHRs for machinery intended for underground work
- Supplementary ESHRs for machinery presenting particular hazards due to the lifting of persons



Annex II

■ Declaration of Conformity

- Now requires the person who is authorized to compile the Technical Construction File to be established in the EU
- If needed the full name and address and identification number of the Notified Body who carried out the Quality system assessment [*See Annexes VIII, IX, X*)



Annex II

■ Declaration of Incorporation

- Now requires the person who is authorized to compile the Technical Construction File to be established in the EU
- Requires sentences:
 - declaring which ESHRs have been applied and fulfilled
 - that the relevant technical documentation complies with Annex VII
 - What other Directives [EMC, etc.) the partly completed machinery complies with
 - That the partly completed machinery must not be put into service until the final machinery into which it is incorporated has been declared inconformity with the provision of this Directive and a DoC has been issued



Annex II

■ Custody

- The original EC Declaration of Conformity or EC Declaration of Incorporation must be kept for 10 years from the last date of manufacture



Annex III

■ CE Marking

- Standard CE Marking using only the CE letters
- No date is required
- If a full quality assurance procedure has been applied then the CE Marking must be followed by the identification number of the Notified Body (for Annex IV products)



Annex IV

- These products are included in Annex IV:
 - Circular saws (single or multi-blade), band saws, and sawing machinery for use with wood and material with similar characteristics or for working with meat and material with similar characteristics
 - Hand-fed surface planing machinery
 - Thicknessers with a built in mechanical feed device
 - Combinations of any of the above
 - Hand-fed tensioning machinery
 - Hand-fed vertical spindle molding machinery
 - Portable chainsaws for woodworking
 - Presses and press brakes for cold working of metal with travel $>6\text{mm}$ and a speed $>30\text{mm/s}$
 - Injection or compressions molding machinery for plastics or rubber



Annex IV

- Machinery for underground work (no longer includes combustion engines for use in underground work – they are partly completed machinery)
- Manual load trucks for household gold refuse collection
- Removable mechanical transmission devices and their guards
- Guards for removable mechanical transmission devices
- Vehicle servicing lifts
- Devices for the lifting of persons or of persons and goods involving a hazard of falling >3m
- Portable cartridge operated fixing and other impact machinery
- Protective devices for the detection of persons
- Power operated interlocking movable guards designed to be used as safeguards in presses, pres-brakes and injection or compression machinery
- Logic units to ensure safe functions
- Roll-over protective structures (ROPS)
- Falling-object protective structures (FOPS)



Annex V

- This provides a list of Safety Devices previously referred to in the Scope as item C



Annex VI

- Assembly instructions for partly completed machinery
 - Must contain a description of what must be done to make it part of complete machinery without compromising safety and health
 - Must be in an official Community language acceptable to the manufacturer of the complete machinery, or his authorized representative



Annex VII

- Technical file for machinery – completed or partly completed, as relevant
 - General description
 - Overall drawing and drawing of control circuits
 - Theory of operation
 - Full detail drawings with any calculations, test data, certificates, etc., sufficient to show conformity with relevant ESHRs
 - Documentation for a risk assessment listing applicable ESHRs and documentation for protective measures implemented to eliminate hazards and to reduce risks
 - Standards and other technical specifications used identifying the ESHR each one covers
 - Technical reports and tests data



Annex VII

- Manuals for the machinery – installation, user, maintenance, service
- DoI and assembly instructions for any partly completed machinery that has been incorporated
- DoC for any machinery or other products incorporated into the machinery
- A copy of the DoC for this product
- For series manufacture the internal measure that will ensure production remains complaint [e.g., quality system, incoming inspection process for components, production line tests, etc.
- Technical File need not remain in the EU, but must be presented on reasonable request to a competent national authority by the person named in the DoC/I



Annex VIII

- Assessment of conformity with internal checks on the manufacture of machinery
 - This annex requires the technical file to be completed
 - Manufacturer must take all measures necessary in order that the manufacturing process ensures compliance of the manufactured product with the technical file



Annex IX

- EC type examination
 - For products covered in Annex IV
 - Details the steps for submitting the product to a notified body
 - The manufacturer and the notified body will retain the technical file and certificates for 15 years from the date of issue of the certificate
 - Must be renewed not more than every 5 years



Annex X

■ Full quality assurance

- Primary use is for Annex IV products
- Discusses the process for a full quality assessment review and approval
- This annex does not mention ISO 9000 series or one of the other quality systems, but it is the same process
- Unknown is that the Annex requires a notified body to carry this out, and most current ISO 9000 series Certificates are issued by an Accredited Registrar *[this may end up being decided by the Court at some point]*



Annex XI

- Minimum criteria to be taken into account by Member States for the notification of bodies
 - Discusses how notified bodies shall operate



References and resources

- <http://www.machinebuilding.net/n/n0750.htm>
 - Free Guide to the New Machinery Directive 2006/42/EC
 - Risk Calculator

- http://ec.europa.eu/enterprise/mechan_equipment/machinery/nd_workshop/index.htm
 - From a Workshop held in May 2007 but there are links to the presentations

- <http://www.hs-compliance.com/Info/TechnicalInformation/Machinery.aspx>
 - Health and Safety Compliance Engineering with links to downloadable copies of the old and new Machinery Directives



References and resources

- <http://www.pilz.com/company/news/sub/company/articles/02604/index.en.jsp>
 - Pilz International a good reference for machinery safety
- <http://hesa.etui-rehs.org/uk/publications/pub43.htm>
 - By ETU-I-REHS and KAN, “A tool to uncover the changes introduced by the revised directive
 - And of course a search of the internet will turn up additional articles and any that come out after this presentation



And in conclusion

YOU need to:

- Read one of the explanatory guides and make decisions for yourself and your company
- Determine what applies to your product
- Determine how the new Directive will be implemented within your firm
- Decide if you need external resources to assist in interpretation and implementation
- Determine what products will continue to be sold into the EU on or after December 29, 2009, and what if any changes must be made to them, to the technical construction file, and to the DOC or DoI